

K053453

**510(k) Summary for Honeywell HomMed Central Station**

Submitter: Honeywell HomMed, LLC  
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Brookfield, Wisconsin 53045  
Corporate Contact: Michael Leigh, Director of Regulatory/Quality  
Honeywell HomMed, LLC  
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Establishment Registration #: 3004183721  
Submission Contact: Tommie J. Morgan Ph.D., President  
Morgan Consultants, Inc.  
2018 North Durham  
Houston, Texas 77008  
Ph: (713) 880-5111  
Fax: (713) 880-3494  
Trade Name: Central Station, Version 3.5  
Predicate Device: HomMed Central Station  
Common Name: Patient Vital Signs Monitor Viewing Station  
Classification Name: Non-Invasive Blood Pressure Measurement System  
Product Code: DXN

**Intended Use:**

Central Station's intended use is to retrospectively receive, display and store monitored vital signs parameters and related data. The Central Station displays the data and system alerts for review and interpretation by a healthcare professional. Central Station is not intended for emergency use or real-time monitoring.

**Performance Data:**

Central Station is a software system that operates on a commercially available PC system with the minimum performance specifications consistent with typical PC hardware and equipment specifications. Central Station accepts data from Honeywell HomMed Patient Monitors (Sentry and Genesis) as well as the Honeywell HomMed MedPartner. The software validation results demonstrated that the Central Station 3.5 System was in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements for software.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding medical device software.



## STERILIZATION STATEMENT OF NON-APPLICABILITY

### STERILIZATION INFORMATION

Sterilization issues do not apply to this Honeywell HomMed Central Station and associated hardware components or attachments used with Central Station because they are not supplied sterile nor are they intended to be used in sterile environments or applications unless noted.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Honeywell HomMed, LLC  
c/o Mr. Tommie J. Morgan Ph.D.  
President  
Morgan Consultants, Inc.  
2018 North Durham  
Houston, Texas 77008

Re: K053453

Trade Name: HomMed Central Station, Version 3.5  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Non-Invasive Blood Pressure Measurement System  
Regulatory Class: Class II (two)  
Product Code: DXN  
Dated: April 21, 2006  
Received: April 27, 2005

Dear Mr. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Page 2 – Mr. Tommie J. Morgan Ph.D.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman" followed by a stylized flourish.

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K053453

Device Name: Central Station, Version 3.5

### Indications For Use:

Central Station's intended use is to retrospectively receive, display and store monitored vital signs parameters and related data. The Central Station displays the data and system alerts for review and interpretation by a healthcare professional. Central Station is not intended for emergency use or real-time monitoring.

Prescription Use X  
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K053453

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